

**REMARKS**

Claims 64, 66, 68 and 70-76 have been amended. Claims 63-76 are pending in this application.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**I. OBJECTIONS TO THE SPECIFICATION AND CLAIMS**

The examiner objects to the specification on several grounds. In some cases, applicants have chosen to amend the specification in view of the examiner's remarks. As the USPTO experienced difficulty when processing parent application USSN 09/244,984, which like the instant application had been amended via replacement section (37 C.F.R. § 1.121(2)), and requested that applicants provide a substitute specification to facilitate publication of the issued patent, applicants enter the present amendments via substitute specification.

In accordance with 37 C.F.R. §§ 1.121(3) and 1.125, applicants submit a marked-up version of the substitute specification showing all changes to the specification of record, in addition to a clean form of the document, and assert that the substitute specification contains no new matter.

In paragraph 4 of the Office Action, the examiner objects to a missing sequence identifier. Applicants assert that the amendments submitted herein obviate the objection.

In paragraph 5, the examiner objects to an amendment filed September 24, 2001 for allegedly introducing new matter. Applicants traverse the rejection and have filed a petition to the Group Director in order to review the rejection. A copy of the filed petition is enclosed.

The examiner, in paragraph 6, asserts that references to the "1-477" fragment and particular amino acid residues are unclear without correlating such references to particular SEQ ID NOs. With respect to the "1-477" fragment, the specification states that the "1-477" fragment corresponds to the signal peptide and the pro and catalytic domains of TACE as disclosed in Black *et al.*, *Nature*, 385:729-733 (1997), which the specification incorporates by reference. *See e.g.* Substitute specification, paragraph spanning pg. 11-12; pg. 32, ln. 14-17. Applicants submit herewith a supplemental sequence listing comprising new SEQ ID NO. 8, which corresponds to the "1-477" fragment.

Regarding citation of particular amino acids, the specification states that references therein to amino acid sequences of TACE refer to the sequence disclosed in Black *et al.* See e.g. Substitute specification, paragraph spanning pg. 11-12. Thus, an artisan reviewing the specification would recognize instantly the referenced residue. Accordingly, applicants submit that repetitive citations to the referenced sequence are not required. To further simplify matters, applicants submit herewith a supplemental sequence listing comprising new SEQ ID NO. 7, which corresponds to the TACE amino acid sequence disclosed in Black *et al.*

In paragraph 7, the examiner objects to the recitation of both Asn542 and Asn452. The examiner correctly notes that Asn 542 is a typographical error. See SEQ ID NO. 7. Applicants believe the amendments obviate the objection.

The examiner also requests clarification regarding a reference to Cys478, apparently because the residue is located outside the 1-477 fragment. The specification correctly identifies the residue as a pivot point for the disintegrin domain. Therefore, applicants believe no clarification is required.

The examiner, in paragraph 8, objects to the use color figures. Applicants traverse the objection, as they already have filed a Petition to Accept Color Drawings in this case. See Petition filed March 29, 2001 in USSN 09/611,722.

In paragraph 9, the examiner objects to a reference to WO 95/07619. Applicants believe the amendments obviate the objection.

The examiner also objects to claim 68 for an omitted conjunction. Applicants believe the amendments obviate the objection.

## **II. REJECTIONS UNDER 35 U.S.C. § 112 ¶2**

The examiner rejects claims 67 and 74-76 under 35 U.S.C. §112, ¶2, for alleged indefiniteness. According to the examiner, “[t]he additional limitations in Claims 67 and 74 are confusing as to the physical limitations they impose on the claimed computerized system.” Office Action, pg. 5, ¶11.

Applicants respectfully disagree. The commonly applied test for the requisite precision is whether one skilled in the art would understand the metes and bounds of the claim when read in light of the specification. See *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). Claims 67 and 74 are directed to, *inter alia*, computerized systems for depicting and analyzing TACE polypeptides wherein the data structure of the

memory of the computerized system is organized in a particular way. For example, the claimed computerized systems comprise at least one first-type storage region, comprising a set of spatial coordinates of a TACE polypeptide in a multi-dimensional space and at least one second-type storage region, comprising a representation of characteristics of a plurality of amino acids of the polypeptide. The second-type storage region is logically associated with the first-type storage region to support data processing in the processor. Furthermore, the specification describes the nature of the data structure. *See e.g.* Substitute specification, pg. 30-32. Accordingly, applicants assert that an artisan would understand the metes and bounds of the claimed invention in light of the specification. Applicants request, therefore, that the rejection be withdrawn.

### III. REJECTIONS UNDER 35 U.S.C. § 112 ¶1

The examiner rejects claims 63-65 under 35 U.S.C. §112, ¶1, for allegedly failing to convey to one of skill in the art that the applicants possessed the claimed invention at the time the application was filed. According to the examiner, “[t]he concept of a computer readable medium comprising two program codes, one for data storage and one for data processing, is considered new matter.” Office Action, pg. 6, ¶2.

In levying a written description rejection, an examiner has the burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicant’s disclosure, a description of the invention defined by the claims. *See In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976). Applicants assert that the examiner has failed to meet this burden.

The fundamental factual inquiry regarding the adequacy of disclosure is whether the application conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the claimed invention. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). To provide descriptive support, it is not necessary that the application describe the claim limitations exactly. *See e.g. In re Lukach*, 442 F.2d 967, 969 (CCPA 1971)([T]he invention claimed does not have to be described in *ipsis verbis* in order to satisfy the description requirement of § 112.) Rather, the application need only be sufficiently clear that persons of skill in the art would recognize that the applicant had possession of the claimed invention. *See In re Wertheim*, 541 F.2d at 263.

Thus, the written description requirement is satisfied when each claim limitation is supported explicitly, implicitly or inherently in the originally filed disclosure. *See* Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶1, "Written Description" Requirement, 66 Fed. Reg. 1099 (2001).

According to the specification, the inventive computer systems can utilize any general purpose processor. *See e.g.* Substitute specification, pg. 30-32. As a matter of fact, general purpose processors operate only via program codes. Thus, one of skill in the art would recognize instantly that applicants, at the time of the invention, possessed computer-readable media with the claimed program codes. Accordingly, applicants respectfully request that the rejection be withdrawn.

The examiner also rejects claims 66-76 under 35 U.S.C. §112, ¶1, for allegedly failing to convey to one of skill in the art that applicants possessed the claimed invention at the time the application was filed. Applicants assert that the examiner has failed again to satisfy the requisite burden. In particular, the examiner has failed to proffer any evidence of why a person skilled in the art would not recognize in applicant's disclosure, a description of the invention defined by the claims. Indeed, in support of her rejection, the examiner merely asserts that the language of the instant claims differs from that of the original claims. Contrary to the examiner's assertion, however, the language of originally-filed claims is not dispositive as to whether an applicant possessed the claimed invention at the time of filing. Accordingly, applicants request the rejection be withdrawn.

The examiner also rejects claims 63, 65 and 66-76 under 35 U.S.C. §112, ¶1, for allegedly failing to convey to one of skill in the art that applicants possessed the claimed genus. According to the examiner, the specification fails to provide a representative number of species for the claimed genus. Applicants respectfully disagree.

The claimed invention is directed to computer-readable media and computerized systems for depicting and analyzing TACE polypeptides. The computer-readable media and computerized systems comprise structural data obtained from crystallographical analysis of a catalytic domain of a TACE polypeptide. The term "TACE polypeptide," as used in the present application, denotes those polypeptides capable of cleaving the 26kD cell membrane-bound form of TNF- $\alpha$  into the soluble 17 kD form. *See e.g.* Substitute specification, pg. 11, ln. 16-18. The catalytic domain of TACE performs this cleavage. Thus, applicants have demonstrated possession of the claimed genus by disclosing the relevant structure responsible

for the functionality that defines the genus. *See* Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶1, "Written Description" Requirement, 66 Fed. Reg. 1099 (2001). Thus, an inquiry into the number of representative species is unwarranted. Accordingly, the examiner has erred by objecting to the number of representative species. Applicants, therefore, request that the rejection be withdrawn.

### III. REJECTIONS UNDER 35 U.S.C. §§ 102 & 103

The examiner rejects claims 66-69 and 74-76 under 35 U.S.C. §102(a) as allegedly being anticipated by Cirilli. The examiner further rejects claims 70-73 under 35 U.S.C. §103 for allegedly being unpatentable over Cirilli.

Applicants have amended the claims to recite that the structural data was obtained from crystallographical analysis of TACE. Cirilli does not teach or suggest such structural data. Accordingly, applicants believe the amendments obviate the rejection.

\*\*\*\*\*

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date Oct 1, 2004

By Reg No. 34,717

FOLEY & LARDNER LLP  
Washington Harbour  
3000 K Street, N.W., Suite 500  
Washington, D.C. 20007-5143  
Telephone: (202) 672-5571  
Facsimile: (202) 672-5399



Stephen A. Bent  
Attorney for Applicant  
Registration No. 29,768